



IRISH MEDICINES BOARD
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- APRIL 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
IGFBP-3 ELISA Reagent Kit	Beckman Coulter Inc	Advice regarding the review of patient results/patient recall/sample retesting is required	30 March 2011	Yes
SYNCHRON LX@20/LX@20PRO/LX@i 725 Clinical Systems	Beckman Coulter Inc	Advice regarding the use of the device	05 April 2011	Yes
VITEK 2 Piperacillin/Tazobactam Test (AIX Software)	bioMérieux	Advice regarding the use of the device	08 April 2011	Yes
VITEK 2 Piperacillin/Tazobactam Test (PC Software)	bioMérieux	Advice regarding the use of the device	08 April 2011	Yes
T34L Syringe Pump lead screw	CME Limited	Advice regarding a device removal	28 March 2011	Unknown
Codman Hakim Programmable Valve (Inline), Codman Hakim Programmable Valve (Rt. Angle w/Siphon Guard), Codman Hakim Programmable Valve (MICRO), Codman BACTISEAL® Catheter Kit, ACCU-FLO® CSF Reservoir, HOLTER RICKHAM Reservoir (SS Base), HOLTER RICKHAM Reservoir (Plastic Base), Codman External Drainage System 3, MICRO Programmable Valve with Integral Conn., MEDSTREAM Bolus Kit	Codman	Advice regarding a device removal	18 March 2011	Yes
CORTRAK Medical Device used in the placement of CORTRAK Naso-Gastric Tubes	Corpak / Merck Serono	Advice regarding the use of the device	20 April 2011	Yes
Defibtech DDU-100 series AED	Defibtech	Advice regarding a software upgrade	11 March 2011	Yes
ANKYLOS Implant Driver C/X with screwdriver	Dentsply Friadent	Advice regarding the use of the device	17 December 2010	Yes
Isosensitest + 5% Horse Blood + NAD 4mm	Fannin Limited (LIP)	Advice regarding a device removal	01 April 2011	Yes
Carescape Monitor B850	GE Healthcare	Advice regarding a device modification	23 March 2011	Yes
GE Centricity™ PACS; Software Versions: 2.1.x, 3.0.x and 3.1.x	GE Healthcare	Advice regarding a software upgrade	11 February 2011	Yes
TruSat Oximeters and Accessories	GE Healthcare	Advice regarding a device modification	31 March 2011	Yes
Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HDi, Signa Vibrant, GE 1.5T Signa HDe, Optima MR360, Brivo MR355	GE Healthcare	Advice regarding a software upgrade	21 April 2011	Yes
Carescape B650	GE Healthcare	Advice regarding a software upgrade	21 April 2011	Yes
H&W Triad Alco-Prep and Alco-Swab	H&W / Triad	Advice regarding a device removal	19 January 2011	Yes
Dermatome power supply units sold as part of the Padgett Model S and Model S6 products	Integra	Advice regarding a device removal	18 March 2011	Yes
OXFORD Voyager Gate System (Part ref: VOY-700.07500) - Fitted to Voyager Fixed Ceiling Hoist System with X-Y Layout	Joerns Healthcare	Advice regarding the use of the device	17 September 2010	Yes
Ca++ membrane units	Radiometer	Advice regarding the use of the device	13 April 2011	Yes
COBAS AmpliPrep / COBAS TaqMan HCV	Roche Molecular Systems Inc.	Advice regarding the use of the device	04 April 2011	Yes

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Romachair Model 4730 / 4740	Roma Medical	Advice regarding a device modification	02 March 2011	Yes
ARTISTE™, ONCOR™ and PRIMUS™ digital linear accelerators with syngo RT Therapist 4.1 and 4.2	Siemens	Advice regarding the use of the device	13 March 2011	Yes
PERI PREP Wipes Box / SKIN PREP Wipes Box / REMOVE Wipes Box / UNISOLVE Wipes Box / NO STING SKIN PREP Wipes Box	Smith & Nephew	Advice regarding a device removal	21 April 2011	Yes
RENASYS G and RENASYS G/P Dressing Kits / NO STING SKIN PREP Wipes	Smith & Nephew Inc.	Advice regarding a device removal	13 April 2011	Yes
PARADYM ICDs, Models VR 8250, DR 8550, CRT-D 8750 and 8770	Sorin	Advice regarding the use of the device	27 April 2011	Yes
CrystalClear Tracheostomy Tube Cuffed Sterile Pack, CrystalClear Tracheostomy Tube Cuffed Sterile Pack, CrystalClear PDT Sterile and Percutwist Set With CrystalClear Sterile	Teleflex Medical	Advice regarding a device removal	01 April 2011	Yes
THERAKOS™ UVAR XTS™ Procedural Kits Product Codes XT001 & XT125	Therakos, Inc.	Advice regarding a device removal	04 April 2011	Yes
Clinac	Varian	Advice regarding the use of the device	06 April 2011	Yes
Clinac H14, H18, H27, H29	Varian	Advice regarding a device modification	18 April 2011	Yes
EndoVims; V SX10030HD	VIMS	Advice regarding a device modification	17 April 2011	Yes
WaveLight® FS200q	Wavelight GmbH	Advice regarding a software upgrade	18 April 2011	Yes
Ziehm 8000, Compact, Solo, Vision, Vision FD, Vision FD Vario 3D, Vision RFD, Vision R, Vision Vario 3D and Vista plus	Ziehm Imaging GmbH	Advice regarding a device modification	10 February 2011	Yes